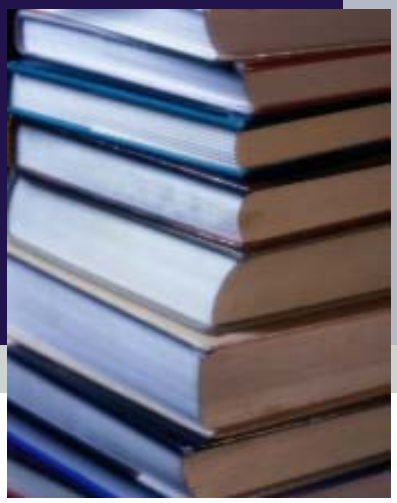
# FAQs: OMB *Information Quality Bulletin for Peer Review*



**Q** How does the OMB *Bulletin* work with other Federal information quality guidelines, such as those issued by the OMB, the HHS, and the NIH?

**A** The OMB *Information Quality Bulletin for Peer Review* (OMB *Bulletin*) supplements other OMB guidance found in the OMB *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* (OMB *Information Quality Guidelines*) (www.whitehouse.gov/omb/fedreg/reproducible2.pdf). In addition, the HHS and the NIH have issued similar information quality guidelines tailored to the information disseminated by the agency. The NIH's implementation of the OMB *Bulletin* must be consistent with the information quality guidelines set forth by the OMB, the HHS, and the NIH.

As background, the OMB issued the Government-wide OMB *Information Quality Guidelines* in February 2002 in response to the Information Quality Act (and prior to developing the OMB *Bulletin*). The OMB *Information Quality Guidelines*, among other things, directed Federal agencies to release and follow their own implementing guidelines. Since October 2002, Federal agencies subject to the Paperwork Reduction Act, such as the NIH, have implemented their own guidelines to help ensure the quality and accuracy of information disseminated to the public. The NIH *Guidelines for Ensuring the Quality of Information Disseminated to the Public* (NIH *Information Quality Guidelines*) (http://ospp.od.nih.gov/infoquality) (1) establish a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated; (2) make available a "complaint process" to correct, as needed, information that the NIH disseminates; and (3) require annual reports to the OMB on complaints the NIH receives under the information quality complaint process.

**Q** When does the OMB *Bulletin* go into effect?

**A** Federal agencies, including the NIH, must implement the OMB *Bulletin* beginning on June 16, 2005.

**Q** Does official NIH scientific information disseminated before June 16, 2005, have to be reviewed in accordance with the OMB *Bulletin*?

**A** No. An information product disseminated by the NIH before June 16, 2005, does not need to be reviewed in accordance with the OMB *Bulletin*, even if the information is "influential." Similarly, if the NIH began the process of reviewing certain information before June 16, 2005, i.e., the NIH already provided a draft report and an associated charge to peer reviewers, then the OMB *Bulletin* peer review process does not apply.

**Q** What is a "dissemination"?

**A** The OMB *Bulletin* covers official NIH "influential scientific information" (ISI) that is disseminated to the public. The OMB *Bulletin* defines "dissemination" as an agency-initiated or -sponsored distribution of information to the public. A dissemination can include information on a public NIH Web site or in an official NIH publication or information an NIH awardee distributes at the specific request of the NIH. The terms

and conditions of the award require the NIH's specific approval of the distribution and/or content of the information. Disseminations also may include information that is:

- Printed in publications that include books, newsletters, brochures, booklets, pamphlets, or reports, including scientific research papers, journal articles, or similar authoritative materials, unless they have disclaimers alerting the audience that they do not represent the official views of the NIH
- Oral in the form of formal speeches, expert testimony, presentations, interviews, or commentaries for publication or broadcast, if they represent the official views of the NIH
- Audiovisual in broadcast scripts, audiotapes, videotapes, or videocasts (e.g., the NIH VideoCasting Web site [http://videocast.nih.gov])
- Electronic via posting on public NIH, Institute or Center (IC) or NIH Office of the Director (OD) Office Web sites

**Q** I'm an intramural NIH scientist who publishes scientific information, but this information represents my views and not those of the NIH. What do I have to do?

**A** Very little. The OMB *Bulletin* covers official NIH scientific information that is "influential" and that is disseminated by the NIH. Usually, an intramural NIH scientist's publication is disseminated by a journal, not by the NIH. In addition, many scientific publications will not be "influential" as the word is defined in the OMB *Bulletin*. As a general matter, when an NIH scientist disseminates information that is not the official view of the NIH, the information should contain a disclaimer to inform the reader. The suggested disclaimer is: *"This presentation (paper) was written by authors in their capacity as NIH employees, but the views expressed in this presentation (paper) do not necessarily represent those of the NIH."*

**Q** How does the NIH interpret "clear and substantial" impact in the definition of ISI?

**A** The NIH has defined "influential" when used in the phrase "influential scientific, financial, or statistical information" to mean that the NIH can reasonably determine, before the information is released, that the dissemination will have or does have a "clear and substantial" impact on important public policies or important private sector decisions or will have important consequences for specific health practices, technologies, substances, products, or firms.

For the NIH to classify information as "influential," the NIH must have a high degree of certainty, based on reasonably sufficient detail, of a genuinely "clear and substantial" impact. The designation of "influential" is applied to information only when it is expected to have a genuinely "clear and substantial" impact rather than a limited, marginal, or incremental effect. A "clear and substantial" impact on major public or private sector policy decisions is one that the NIH determines to have a high probability of occurring. If it is merely arguable that an impact will occur or is a close judgment call, then the impact probably is not "clear and substantial."

**Q** Does the OMB *Bulletin* apply to policy decisions that may be based on ISI?

**A** No. The OMB *Bulletin* covers only scientific information that is "influential" and represents a Federal agency's views. Policy constitutes a Federal agency's course or method of action that is developed to guide and determine present and future decisions and actions. NIH policy decisions may be based on the NIH's evaluation of scientific information. However, although the scientific information underlying NIH policy may be subject to peer review, the policy itself would not be. Accordingly, the NIH's charge to peer reviewers should instruct them to focus only on the scientific information presented for their review, not on any policy that might be based on that scientific information. Policy is exclusively the Federal Government's responsibility.

**Q** If the NIH needs to publicly communicate its decision to halt a clinical trial, does the communication need to be reviewed before the public is informed?

**A** No. The OMB *Bulletin* specifically excludes time-sensitive health and safety determinations such as a communication to halt a clinical trial.

**Q** If the NIH wishes to publicly endorse scientific information from a journal publication that underwent the journal's peer review process, does the NIH also need to peer-review the publication?

**A** Probably not. If the scientific information is "influential," its publication in a refereed scientific journal generally means that adequate peer review has been performed. In the context of scientific and research information and the review process used by scientific journals, the OMB as a general matter regards "technical information that has been subjected to formal, independent, external peer review as presumptively objective." However, the NIH should carefully assess the scientific information to determine whether this presumption is rebuttable. For example, the NIH may prefer to conduct its own peer review of a publication if it determines that a particular journal review process did not address certain questions (e.g., the extent of uncertainty inherent in a finding) that should be addressed before disseminating the information.

**Q** Could the OMB *Bulletin* peer review process delay the publication of a scientific journal?

**A** No. The NIH does not apply the OMB *Bulletin* peer review process to NIH staff publications that are disseminated by a peer-reviewed journal. The NIH considers scientific journal publications to be a dissemination of the journal—not of the NIH. In addition, many such publications would not be "influential" as the word is defined in the OMB *Bulletin*.

**Q** May NIH employees serve on a peer review panel?

**A** Generally not. The OMB *Bulletin* emphasizes the importance of a peer review process that is "independent" of a Federal agency. However, the choice of reviewers requires a case-by-case analysis. Certain exceptions may be made under certain circumstances (e.g., for special Federal Government employees who serve on Federal advisory committees).

**Q** What will the NIH Office of Science Policy and Planning (OSPP) do with IC and NIH OD Office submissions of scientific information?

**A** After receiving recommendations from the Point-of-Contact, the NIH OSPP will affirm whether an information product is ISI and, if so, will review the information product to determine whether it

constitutes a highly influential scientific assessment (HISA). If the information product is either ISI or HISA, the NIH OSPP will discuss with the IC or NIH OD Office Point-of-Contact the type of peer review required. If the information is found to be either ISI or HISA, the NIH OSPP will post the plan for peer review on the NIH public Web site (http://ospp.od.nih.gov/infoquality).

**Q** What kinds of information products *may* be covered by the OMB *Bulletin*?

**A** The OMB *Bulletin* covers non-exempt NIH information products that meet all four of the following criteria:

- Be disseminated by the NIH or a component of an IC or NIH OD Office
- Represent the official views of the NIH or an IC or NIH OD Office
- Contain scientific information
- Be "influential"

A determination of ISI is made on a case-by-case basis by the NIH. In general, there is no single category of information products that automatically qualifies as ISI. However, the NIH *Information Quality Guidelines* provide examples of the types of information disseminated by the NIH that *may* be considered influential. Such examples include NIH recommendations about health practices or medical treatments (e.g., clinical guidelines that will change the standard of care) and NIH research reports disseminated by the NIH as representing the official views of the NIH.

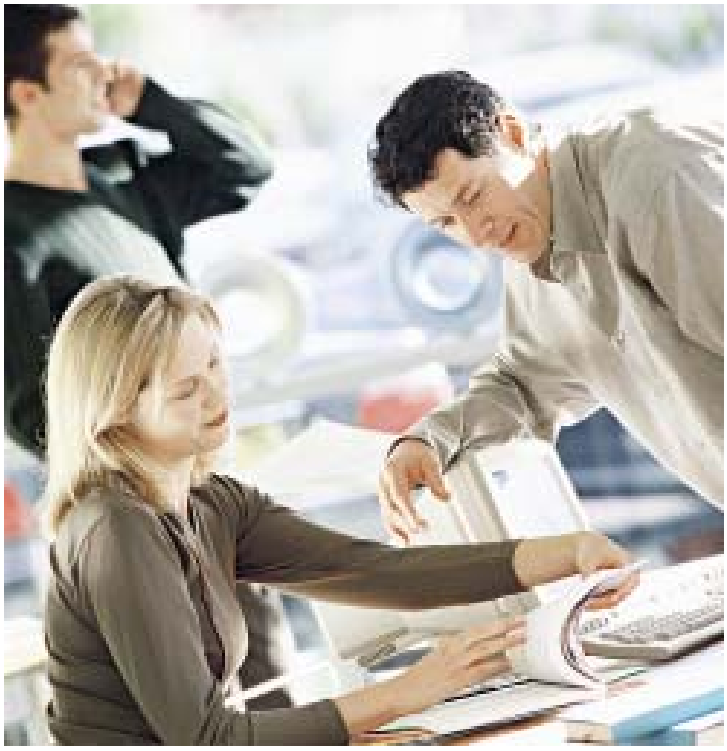
In both cases, scientific information products disseminated by the NIH as its official views are "influential" only if the NIH can reasonably determine in advance that the information product (1) does or will have a clear and substantial impact on important public policies or private sector decisions or (2) will have important consequences for specific health practices, technologies, substances, products, or firms.

**Q** What information is exempt from the OMB *Bulletin* and, therefore, exempt from its peer review process?

**A**
- Distributions limited to Federal Government employees or NIH contractors or grantees (e.g., summary statements).
- Intra-agency or interagency use or sharing of Federal Government information.
- Responses to a request for NIH records under the Freedom of Information Act, the Privacy Act, the

Federal Advisory Committee Act (FACA), the Government Performance Results and Accountability Act, or a similar law.

- Correspondence limited to individuals or persons (e.g., correspondence to one or more Members of Congress but not posted on the NIH Internet or otherwise disseminated by NIH to the public).
- Press releases that support or give public notice of information that the NIH has disseminated elsewhere.
- Archival records and other archival material disseminated by the NIH (e.g., Internet distribution of published articles, including via PubMed, and scientific information from archival tissue and specimen repositories).
- Manuscripts authored by NIH scientists that is to be published in peer-reviewed journals.
- Public filings, subpoenas, or adjudicative processes.
- Distributions for peer review under the OMB *Bulletin*, provided they contain a disclaimer as follows: *"This information is distributed solely for the purpose of predissemination peer review under the applicable information quality guidelines. It has not been formally disseminated by the NIH. It does not represent and should not be construed to represent any NIH determination or policy."*
- National Library of Medicine databases or other archival records (e.g., GenBank and GenPept, sequence and protein databases, and databases populated with archival records or information); CRISP and similar databases (e.g., the NIH Intramural Database, ClinicalTrials.gov, CancerNet/PDQ); and other database systems containing information on research projects and programs supported or conducted by the U.S. Department of Health and Human Services [HHS]).
- Health or safety determinations that are "time-sensitive" (e.g., findings based primarily on data from a recent clinical trial where the trial was adequately peer-reviewed before it began). "Time-sensitive" refers to the need for dissemination to occur because, for example, the HHS cannot practicably or prudently wait for peer review to occur because, the dissemination (1) addresses potential harm or benefit to health or safety or (2) meets a statutory, congressional, court-imposed, or other generally immovable deadline.



- Information disseminated to the public or submitted for peer review before June 16, 2005.
- Influential scientific information disseminated by scientists (not by third parties) employed by the NIH provided that the information contains a disclaimer as follows: *"This presentation (paper) was written by authors in their capacity as NIH employees, but the views expressed in this presentation (paper) do not necessarily represent those of the NIH."* If it is otherwise clear that the information does not represent the official views of the NIH, then no disclaimer is required.
- Draft ISI shared with scientists who are neither Federal Government employees nor NIH awardees for scientific input prior to peer review, provided that it includes a disclaimer as follows: *"The findings and conclusions in this report (presentation) have not been formally disseminated by the NIH and should not be construed to represent any NIH determination or policy."*
- An opinion where the NIH presentation makes it clear (i.e., through a disclaimer such as the one above) that what is being offered is personal opinion rather than fact or the view of the NIH.
- Information supplied to the Federal Government by third parties (e.g., studies by private consultants or companies, private nonprofit organizations, or

research institutions such as universities) that is not endorsed as the official views of the NIH.

- Draft documents, reports, or other draft information products.
- Consensus development conference reports or other third-party views that are not endorsed as the official views of the NIH (e.g., FACA committee reports).
- A document that the NIH has not authored and that has not been adopted as representing the views of the NIH. (By disseminating these materials, the agencies are simply ensuring that the public can have quicker and easier access to materials that are publicly available.)
- Displayed only on intranet (or nonpublic) NIH Web sites.
- IC or NIH OD Office policy positions (e.g., statements of NIH policies such as the Public Access Policy, grants and contract policies, and other policy positions).
- Hyperlinks to a Web page of scientific information that others disseminate.
- Administrative information and information pertaining to basic NIH operations, including information about NIH authorities, activities, and programs; program evaluations and strategic planning documents; contact information for the public; organizational charts; and IC or NIH OD Office directors' status reports.
- Administrative information provided to grant and contract applicants, including solicitations (program announcements [PAs]/requests for applications [RFAs]/requests for proposals [RFPs]) and receipt and review materials (e.g., information for Federal advisory committees, advisory councils, or advisory committee members).
- Accounting, budget, actuarial, and financial information, including information generated or used by Federal agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes, as well as routine statistical information released by Federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends. This includes the Biomedical Research and Development Price Index and budget documents, including congressional justification submissions, congressional appropriations committee reports, and significant items.
- Information products for which an impact cannot be reasonably determined or that are unlikely to have a "clear and substantial" impact (e.g., it is arguable or a close judgment call whether an impact will occur).
- Information that the NIH reasonably determines does or will have a "clear and substantial" impact, but the impact is not on important public policies or important private sector decisions.
- Databases (e.g., TOXNET databases, public use data files, and survey data) that make available to the public NIH scientific information, but such data repositories and other such data compilations are not "influential" by themselves. Such repositories include, but are not limited to, model organism system databases and data repositories mandated by Congress.
- Nonmajor information products or work products that lack substantial scientific or technical content or are derivative and secondary work products such as factsheets, educational programs, conference proceedings, bibliographies (e.g., the Combined Health Information Database and TOXLINE), meeting minutes, and brochures.